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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/688,171

10/17/2003

Craig Bonsignore

CRD-5056

9527

27777 7590 12/19/2006
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EXAMINER

SONNETT, KATHLEEN C

ART UNIT

PAPER NUMBER

3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

12/19/2006

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/688,171	Applicant(s) BONSIGNORE, CRAIG	
	Examiner Kathleen Sonnett	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/13/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/2/2006 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. **Claims 10 and 11** are rejected under 35 U.S.C. 102(e) as being anticipated by Stenzel (U.S. 6,540,777). Stenzel discloses an intraluminal medical device having an unexpanded configuration and an expanded configuration comprising one or more tubular stent segments, each tubular stent segment including a plurality of longitudinal struts being connected on opposite ends by the loop to form a substantially S-shape configuration, and one or more bridging elements extending from one or more of an apex of the plurality of loops. As seen in fig. 11, the bridging elements comprise a first section (112) and a second section (118) that

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extend from one or more of an apex of the plurality of loops and create an interlocking mechanism when the device is in an unexpanded configuration. The second section (118) has a substantially flat surface in proximity to a loop on an adjacent stent segment. The stent may be made of nitinol (col. 9, ll. 63).

4. **Claims 10 and 11** are rejected under 35 U.S.C. 102(e) as being anticipated by Blank (WO 03/075797). Blank discloses an intraluminal medical device having an unexpanded configuration and an expanded configuration comprising one or more tubular stent segments, each tubular stent segment including a plurality of longitudinal struts being connected on opposite ends by the loop to form a substantially S-shape configuration, and one or more bridging elements extending from one or more of an apex of the plurality of loops. As seen in fig. 2, the bridging elements comprise a first section (14b, 16b) and a second section (14a, 16a) that extend from one or more of an apex of the plurality of loops and create an interlocking mechanism when the device is in an unexpanded configuration. The second section (16A) has a substantially flat surface in proximity to a loop on an adjacent stent segment. The stent may be made of nitinol (see page 1).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 12-14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stenzel or Blank in view of Davila et al. (U.S. 6,863,685). Stenzel disclose the invention substantially as described above, further disclosing that the medical device is made of nitinol (col. 9 ll. 63 of

Stenzel; page 1 of Blank). Stenzel and Blank both fail to expressly disclose the amount of nickel and the amount of titanium present in the nickel-titanium alloy.

7. However, Davila et al. discloses that it is old and well known in the art to make a stent from a superelastic alloy of Nitinol. Davila et al. further discloses that it is old and well known in the art to construct a self-expandable stent from an alloy comprising about fifty to about sixty percent Nickel and the remainder titanium. Davila et al. states that the superelastic design of the stent makes it crush recoverable which makes it useful as a stent or frame for any number of vascular devices in different applications (col. 6 lines 32-45). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Stenzel or Blank to include the improvements disclosed by Davila et al. in order to gain the advantages of a medical device that is crush recoverable.

8. Regarding claims 13 and 14, Stenzel and Blank fail to disclose the addition of one or more radiopaque markers.

9. However, Davila et al. discloses that it is old and well known in the art to use radiopaque markers in a stent medical device. Davila et al. further discloses that radiopaque markers ensure proper positioning of the device within a lumen (col. 5, lines 9-11). Also, Davila et al. states that the markers may be positioned at other locations on the stent (col. 12 lines 52-53) and markers may be utilized to determine when and if a stent is fully deployed (col. 10, lines 64-65). Therefore, it would have been obvious to one of ordinary skill in the art to modify Stenzel or Blank to include the improvements made obvious by Davila et al. in order to gain the advantage of being able to ensure proper positioning of the device within a lumen. Positioning the markers into the mating protrusion would have been obvious to one of ordinary skill in order to determine when and if each segment of the stent is fully deployed.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS
11/28/2006


GLENN K. DAWSON
PRIMARY EXAMINER